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No. 89-1879

In the Supreme Court of the United States

OCTOBER TERM, 1990

MICHAEL J. FRIEDRICH, PETITIONER

v.

LOUIS W. SULLIVAN, SECRETARY OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

KENNETH W. STARR
Solicitor General
STUART M. GERSON
Assistant Attorney General
ANTHONY J. STEINMEYER
JOHN S. KOPPEL
Attorneys
Department of Justice
Washington, D.C. 20530
(202) 514-2217

QUESTIONS PRESENTED

1. Whether the Secretary's national coverage determination that chelation therapy is not covered by Medicare Part B is an "interpretative rule" exempt from the notice-and-comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(b)(A).

2. Whether application of that national coverage determination to petitioner's claim for reimbursement for chelation therapy violated his right to due process of law.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A19) is reported at 894 F.2d 829. The opinion of the district court (Pet. App. A22-A35) is unreported. The decision of the Medicare hearing officer (Pet. App. A37-A57) is unreported.

JURISDICTION

The judgment of the court of appeals (Pet. App. A20-A21) was entered on January 25, 1990. A petition for rehearing was denied on March 7, 1990. Pet. App. A58. The petition for a writ of certiorari was filed on May 31, 1990. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Chelation therapy is a treatment for atherosclerosis that involves the intravenous injection of disodium edetate solution. Proponents contend that disodium edetate binds ("chelates") with calcium, thereby facilitating the removal of calcium-containing atherosclerotic plaque from blood vessels. However, chelation therapy has been widely discredited by the general medical community on the grounds that the theory underlying its use is implausible and that its safety and effectiveness have not been demonstrated in controlled clinical trials. See, *e.g.*, *United States* v. *Evers*, 643 F.2d 1043, 1045 (5th Cir. 1981); Pet. App. A3-A4, A26-A27.

The Health Care Financing Administration, which administers the Medicare program, first issued instructions in 1970 that restricted Medicare coverage of disodium edetate to treatment for ailments other than atherosclerosis. Pet. App. A4. These instructions were based on the recommendation of the Public Health Service, which consulted with several medical organizations and governmental agencies, including the Food and Drug Administration. *Ibid.*; see also *id.* at A2-A3. The FDA-approved labeling for the drug has stated that disodium edetate is indicated for the treatment of hypercalcemia and scleroderma, but not for the treatment of atherosclerosis. Pet. App. A4 (citing 35 Fed. Reg. 438 (1970)).

The HCFA instructions on disodium edetate remained in effect until 1980, when HCFA replaced most specific drug coverage determinations with general criteria for intermediary and carrier use in determining coverage. Pet. App. A4. These criteria permitted payment for any use of an FDA-approved drug determined by the carrier to be reasonable and necessary, except for those uses specifically disapproved by the FDA or for which coverage might be precluded by a national instruction. *Ibid.*

Subsequently, HCFA requested the Public Health Service to review chelation therapy and develop a recommendation concerning its suitability for Medicare coverage. Pet. App. A4. The Public Health Service published a *Federal Register* notice announcing its plans to undertake that assessment and requesting interested parties to submit relevant information. *Ibid.* (citing 45 Fed. Reg. 41,222 (1980)). In addition, the Public Health Service separately solicited evaluations of chelation therapy from a number of professional organizations and medical specialty groups, including those groups advocating the treatment. Pet. App. A4; see *id.* at A19.

After considering all the information submitted, the Public Health Service issued a comprehensive report and assessment recommending that the Medicare program not cover chelation therapy. Pet. App. A5. Based on this assessment, HCFA issued in February 1982 a "national coverage determination" that chelation therapy was not covered by Medicare; this determination was incorporated in the Medicare Carriers Manual. *Ibid.* See Pet. App. A5-A6 (quoting the relevant directions in the Medicare Carriers Manual). Carriers paying claims under Part B of the Medicare program, 42 U.S.C. 1395j *et seq.*, and hearing officers adjudicating disputes over such claims are obligated to follow the Manual's instructions.[1]

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[1] As the Court noted in *Schweiker* v. *McClure*, 456 U.S. 188, 189-190 (1982), the Medicare program consists of two parts. Part A, which is not at issue in this case, provides insurance against the costs of institutional health care. Part B covers a portion (usually 80%) of the reasonable charge for certain physician services, outpatient physical therapy, X-rays, laboratory tests, and other medical and health care. The Secretary of Health and Human Services has contracted with private carriers to pay qualifying Part B claims on his behalf. See 42 U.S.C. 1395u (1982 & Supp. V 1987).

Part B of Medicare does not cover services that are not medically "reasonable and necessary." 42 U.S.C. 1395y(a)(1)(A) (1982 &

2. a. Petitioner began receiving chelation therapy for treatment of atherosclerosis in 1983 and filed claims for payment under Medicare Part B. The Medicare carrier denied the claims on the basis of the direction in the Medicare Carriers Manual. At his hearing before a hearing officer appointed by the carrier, petitioner presented the testimony of his treating physician and submitted materials containing anecdotal evidence and uncontrolled "trials" that purported to demonstrate the effectiveness of chelation therapy. The carrier hearing officer relied upon the Manual instructions regarding chelation therapy in upholding the denial of coverage. Pet. App. A37-A57.

b. Petitioner then commenced this action. By agreement of the parties pursuant to 28 U.S.C. 636(c), the case was referred to a magistrate for decision. The parties cross-moved for summary judgment, and the magistrate granted petitioner's motion. Relying on a 1975 decision by the Appeals Council of the Social Security Administration that allowed reimbursement for chelation therapy under Part A of Medicare, the magistrate ruled that the 1982 instructions

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Supp. V 1987). When a Part B carrier has been billed for a particular medical service, the carrier determines whether the service satisfies this standard and is otherwise covered under Part B; the carrier also establishes the "reasonable charge" that may be paid for covered services and items. 42 U.S.C. 1395u(a); 42 C.F.R 405.803, 421.200. A claimant is entitled to challenge the carrier's determination by means of a "review determination" (a procedure involving the submission of written materials) and, as to disputes over $100 or more, an oral hearing before a hearing officer selected by the carrier. 42 U.S.C. 1395u(b)(3)(C) (1982 & Supp. V 1987); 42 C.F.R. 405.807-405.812, 405.820-405.860. See *Schweiker* v. *McClure*, 456 U.S. at 191.

In administering the Medicare program, the carrier and any hearing officer are bound by the Medicare statute, the regulations, and the instructions and guidelines issued by the Secretary in his capacity as administrator of the Part B program. 42 C.F.R. 405.860. See *Schweiker* v. *McClure*, 456 U.S. at 197.

"represented a change in the policy of the Secretary, as opposed to a mere clarification of an existing regulation." Pet. App. A31-A32. Thus, the magistrate reasoned, the instructions "are substantive rather than interpretative and are subject to the notice and comment provisions of the A.P.A." *Id.* at A32. Because the instructions on chelation therapy had not been promulgated in accordance with those procedures, the magistrate held the instructions invalid as applied to petitioner's claim. *Id.* at A33. The magistrate also held that petitioner's right to due process entitled him to a ruling on his chelation therapy claim without reference to invalid instructions. *Id.* at A34.

3. The court of appeals reversed and remanded with instructions to dismiss the complaint. Applying general principles articulated by the D.C. Circuit in *General Motors Corp.* v. *Ruckelshaus*, 742 F.2d 1561, 1565 (1984), cert. denied, 471 U.S. 1074 (1985), and approved in subsequent Sixth Circuit decisions, the court of appeals held that the Secretary's national coverage determination is an interpretative rule exempt from the notice-and-comment requirements of the APA. Pet. App. A10-A17.[2]

The court rejected petitioner's contention that the chelation therapy instructions at issue were a departure from prior practice, explaining that "[t]he record as a whole convinces us that the Secretary has been consistent in his determina-

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[2] The principles that the court applied in determining whether the national coverage determination was interpretative (as opposed to substantive or legislative) were as follows (Pet. App. A11 (quoting from *General Motors Corp.* v. *Ruckelshaus*, 742 F.2d at 1565)):

> First, the agency's own label, while relevant, is not dispositive. . . . An interpretative rule simply states what the administrative agency thinks the statute means, and only " 'reminds' affected parties of existing duties." . . . On the other hand, if by its action the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule.

tion that Chelation therapy is not reasonable and necessary for the diagnosis or treatment of atherosclerosis." Pet. App. A13-A14. The magnitude of that coverage determination's potential impact on Medicare beneficiaries was not a proper factor on which to rely in determining whether the determination was an interpretative rule, the court continued, nor could the determination be considered a "gap-filling" substantive rule. *Id.* at A14.

The court observed that "[n]ational standards are essential if there is to be uniformity and equality in the administration of Medicare," and that "[i]t is inconceivable * * * that the Secretary might be required to comply with the full panoply of APA notice and comment requirements in promulgating national standards for individual drugs and medical procedures." Pet. App. A16. The national coverage determination does not " 'fill the gaps' in the statute," " 'supplement' it," or create new law, the court concluded, but rather "interprets the statutory language 'reasonable and necessary' as applied to a particular medical service or method of treatment." *Id.* at A17. Accordingly, the court held, the magistrate "erred in concluding that the determination is a legislative rule and therefore is invalid for failure of the Secretary to comply with the requirements of 5 U.S.C. § 553(b)." *Ibid.*

Finally, the court determined that petitioner was not denied due process by the application of the instructions on chelation therapy to his claim. The court stated that its reversal of the magistrate's determination that the national coverage determination was invalid had eliminated that ground for petitioner's due process claim. Noting that "[petitioner] had no more than a unilateral expectation that he would receive reimbursement under the Medicare program for chelation therapy" and that the Secretary had relied on voluminous materials in issuing the coverage determination, the court also held that petitioner "does not have a due

process right to have his individual claim considered *de novo* in the face of the Secretary's determination." *Id.* at A18, A19.

ARGUMENT

In characterizing the national coverage determination as an interpretative rule, the court of appeals correctly applied well-established principles to this particular directive. Congress has provided that with respect to services provided after January 1, 1987, national coverage determinations shall not be overturned on the basis of a failure to comply with the APA's notice-and-comment provision. Thus, the court's decision on this question has little, if any, prospective importance. Petitioner's due process claim is without merit. Further review is therefore unwarranted.

1. a. The APA specifically excludes "interpretative" rules from its notice-and-comment procedures. 5 U.S.C. 553(b)(A). Although in some cases the question whether a particular rule is interpretative can present a difficult issue of line drawing, certain general principles have achieved widespread acceptance. The court of appeals applied those principles here.

The Attorney General's Manual on the APA defines interpretative rules as "rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." United States Department of Justice, *Attorney General's Manual on the Administrative Procedure Act* 30 n.3 (1947 & photo. reprint 1979).[3] Thus, interpretative rules are those that do not

[3] The courts have given deference to the interpretations of the Attorney General's Manual "because of the role played by the Department of Justice in drafting [the APA]." *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 546 (1978).

"grant or deny rights" or "impose obligations which do not already exist in the statute." *Cabais* v. *Egger*, 690 F.2d 234, 238 (D.C. Cir. 1982). See *Gibson Wine Co.* v. *Snyder*, 194 F.2d 329, 331 (D.C. Cir. 1952). In issuing an interpretative rule, an agency does not require or rely upon delegated authority to make law. See, *e.g.*, *American Postal Workers Union* v. *United States Postal Serv.*, 707 F.2d 548, 558-559 (D.C. Cir. 1983), cert. denied, 465 U.S. 1100 (1984).

"Substantive" rules (also called "legislative" rules), by contrast, "create law, usually implementary to an existing law." *Allen* v. *Bergland*, 661 F.2d 1001, 1007 (4th Cir. 1981). Thus, substantive rules have "effect[s] *completely independent* of the statute." *Cabais* v. *Egger*, 690 F.2d at 238 & n.9 (quoting *Gibson Wine Co.* v. *Snyder*, 194 F.2d at 331).

The court of appeals conducted its analysis of the 1982 national coverage determination in accordance with these principles. Relying on *General Motors Corp.* v. *Ruckelshaus*, *supra*, and two of its own decisions that had applied a similar approach, the court considered whether the Secretary's determination on chelation therapy "simply states what the administrative agency thinks the statute means" or, on the other hand, was intended "to create new law, rights or duties." Pet. App. A11. The court concluded that the Secretary's instruction to deny coverage "creates no new law," but rather "interprets the statutory language 'reasonable and necessary' as applied to a particular medical service or method of treatment." Pet. App. A17. Petitioner does not argue that the general principles on which the court relied are incorrect or inconsistent with those applied by other courts of appeals in comparable cases. The application of those principles to the particular administrative directive at issue here—"an extraordinarily case-specific endeavor," *American Hosp. Ass'n* v. *Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987)—presents no question calling for this Court's review.

In any event, the court's analysis of the national coverage determination is correct. In promulgating an instruction that chelation therapy is not covered by Medicare Part B, the Secretary did not exercise delegated power to make law apart from that embodied by the statute. Rather, he determined that a particular procedure, chelation therapy, is not "reasonable and necessary for the * * * treatment of illness or injury" within the meaning of the Medicare statute, 42 U.S.C. 1395y(a)(1)(A) (1982 & Supp. V 1987). See *American Postal Workers Union*, 707 F.2d at 559 (in changing an annuity computation formula, agency was merely interpreting the statutory term "average pay"); *Energy Consumers & Producers Ass'n* v. *Department of Energy*, 632 F.2d 129, 139-141 (Temp. Emer. Ct. App.) (agency rule interpreting statutory exemption for "stripper wells" was exempt from notice-and-comment requirement), cert. denied, 449 U.S. 832 (1980). Contrary to petitioner's contention (Pet. 10), the fact that the Secretary's determinations are binding upon agency and carrier employees that administer the Medicare Part B program does not alter their interpretative nature.[4]

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[4] As the court of appeals found (Pet. App. A12-A14), the national coverage determination on chelation therapy was not a departure from longstanding agency practice; there is thus no merit to petitioner's contention (Pet. 9) that prior to 1980 the Secretary allowed insurance carriers and hearing officers to determine "on a case by case basis" whether chelation therapy to treat atherosclerosis was reimbursable under the Medicare Act. In any event, the fact that an agency directive may change an agency's position does not require the conclusion that the directive is a substantive rule. See *Michigan* v. *Thomas*, 805 F.2d 176, 182-184 (6th Cir. 1986) (holding that "[a]n administrative agency may reexamine its prior decisions and may depart from its precedents provided the departure is explicitly and rationally justified" and that memorandum first articulating a new interpretation of the Clean Air Act was an interpretative rule that did not require notice-and-comment rulemaking under the APA); *Alcaraz* v. *Block*, 746 F.2d 593, 613 (9th Cir. 1984) ("[t]hat the regulations may have altered administrative duties or other

An agency is not obligated to promulgate a substantive rule in order to require officials acting under the agency's authority—including, in this case, hearing officers bound by the Secretary's contracts with Part B carriers, see p. 3 & note 1, *supra*—to adhere to the agency's considered interpretation of a statute it administers.

b. Section 9341 of the Omnibus Budget Reconciliation Act of 1986, 42 U.S.C. 1395ff(b)(3)(B) (Supp. V 1987), provides that a national coverage determination "shall not be held unlawful or set aside on the ground that a requirement of section 553 of title 5 * * *, relating to publication in the Federal Register or opportunity for public comment, was not satisfied."[5] This provision is applicable to claims for goods or services furnished on or after January 1, 1987. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9341(b), 100 Stat. 2038. Thus, with respect to claims for items or services furnished during the last three-and-a-half years or to be furnished in the future, Congress has foreclosed the claim—advanced by petitioner in this

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hardships does not make them substantive"); *American Postal Workers Union*, 707 F.2d at 558-560 (holding that agency's new method of computing annuities was interpretative rule, despite fact that it changed old method).

The court of appeals' conclusion is consistent with decisions on similar directives issued under Medicare. See, *e.g.*, *St. Mary's Hosp.* v. *Blue Cross & Blue Shield Ass'n*, 788 F.2d 888 (2d Cir. 1986) (Medicare Providers Reimbursement Manual); *Bio-Medical Applications of Providence, Inc.* v. *Heckler*, 593 F. Supp. 1233 (D.D.C. 1984) (Medicare Renal Dialysis Facility Manual), aff'd mem., 776 F.2d 365 (D.C. Cir. 1985).

[5] Section 1395ff(b)(3) also provides that a national coverage determination is not subject to review by an administrative law judge, and that a court, on finding inadequate support for the determination, may not substitute a revised determination that the service or item is covered but instead must remand the matter to the Secretary to supplement the record.

case—that national coverage determinations are invalid unless promulgated in accordance with the APA's notice-and-comment requirements for substantive rulemaking. Consequently, the question whether the court of appeals correctly characterized the rule at issue in this case has little, if any, prospective importance.

2. Petitioner also contends (Pet. 10-11) that even if the 1982 national coverage determination is a valid interpretative rule, due process entitles him to an administrative determination of his claim by a hearing officer who is not bound to follow it. This contention, if accepted, would mean that each Medicare Part B claimant would have a constitutional right to a determination by a hearing officer of the issue whether, despite a valid interpretative rule to the contrary, a particular treatment is reasonable and necessary within the meaning of the Medicare statute.

Petitioner cites no authority whatever for this position—which would mandate a perverse regime for the administration of the Nation's multi-billion dollar Medicare program. As the court of appeals recognized, "National standards are essential if there is to be uniformity and equality in the administration of Medicare." Pet. App. A16. Implementation of such standards requires, in turn, that the Secretary be able to assemble information on the general effectiveness and safety of medical procedures and to issue instructions embodying his judgments that are binding on those who act on his behalf. The Constitution does not require that each hearing examiner be empowered to reconsider those decisions. Cf. *Heckler* v. *Ringer*, 466 U.S. 602, 617 (1984) (noting, with respect to Part A Medicare claim, "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions"); *Federal Power*

Comm'n v. *Texaco Inc.*, 377 U.S. 33, 39 (1964) (Commission is not precluded "from particularizing statutory standards through the rule-making process and barring at the threshold those who neither measure up to them nor show reasons why in the public interest the rule should be waived."); *Hatcher* v. *Heckler*, 772 F.2d 427, 432-433 n.9 (8th Cir. 1985) ("[i]f * * * [hearing] officers were allowed to disregard HCFA guidelines in the exercise of their discretion during a hearing, the uniformity of result obviously needed in such a massive system of claims determination would suffer").

Agents of an administrative agency may constitutionally be obligated to follow the agency's interpretative rules, leaving to whatever judicial review is available the question of the rules' consistency with the governing statute.[6] Petitioner's contention that under the Constitution, a Medicare Part B

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[6] Interpretative rules are not binding on courts to the same degree as are legislative rules. Rather, as this Court explained in *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944), interpretative rules,

> while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it the power to persuade, if lacking power to control.

Because the Secretary's instructions regarding chelation therapy rest on "factual premises within [the agency's] expertise," they are entitled to very substantial deference. *Bureau of Alcohol, Tobacco & Firearms* v. *FLRA*, 464 U.S. 89, 98 n.8 (1983). Petitioner does not seek review in this Court of the correctness of the Secretary's application of the statute to chelation therapy. Rather, the petition is limited to the questions whether the rule was adopted in violation of the APA and whether its binding effect on the hearing officer is consistent with due process. Pet. i.

hearing officer must be allowed to reconsider the Secretary's national coverage determinations presents no question calling for this Court's review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

KENNETH W. STARR
Solicitor General
STUART M. GERSON
Assistant Attorney General
ANTHONY J. STEINMEYER
JOHN S. KOPPEL
Attorneys

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